UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| APPLICATION NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
|---|---|---|---|
| 08/473,789 | 06/07/95 | CURTISS R | MEGAN-100-21 |

EXAMINER

HM32/1113

PATREA L PABST
ARNALL GOLDEN & GREGORY
2800 ONE ATLANTIC CENTER
1201 W PEACHTREE STREET
ATLANTA GA 30309-3450

| ART UNIT | PAPER NUMBER |
|---|---|
| 1641 | 25 |

DATE MAILED: 11/13/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on July 27, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) 1-5, 8-14, 16, 20, 23, 24, 27-29, 37 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-5, 8-14, 16, 20, 23, 24, 27-29, 37 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

**--SEE OFFICE ACTION ON THE FOLLOWING PAGES--**



★ U.S. GPO: 1998-421-632/40...

**DETAILED ACTION**

The Group and/or Art Unit location of your application in the Patent and Trademark Office has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1641.

The text of those sections of U.S. Code not included in this Office Action can be found in a prior Office Action.

The Examiner acknowledges receipt of the Appeal Brief filed July 27, 1998.

***Response to Arguments***

In view of the Appeal Brief filed on July 27, 1998, PROSECUTION IS HEREBY REOPENED. A new grounds of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(a) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(b) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

### *Claim Rejections - 35 USC § 112*

Claims 1-5, 8-14, 16, 20, 23, 24, 27-29, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite the limitation "permissive" and "non-permissive". The terms are relative and there is no clear definition in the specification. Since the terms are relative, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

### *Claim Rejections*

*35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

*35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 8, 10-14, 16, 20, 23, 24, 27-29, and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Szafranski et al.

Szafranski et al (US Patent #5,681,745) disclose a genetic containment system which expresses a biotin-binding component

that can be used for destroying recombinant cells. (See especially Abstract)

In addition, Szafranski et al disclose that the system is comprised of a suicide cassette that encodes a biotin-binding component.

Moreover, Szafranski et al disclose that the system is comprised of a second gene that controls the suicide gene. Expression of the suicide gene is also controlled by a regulatable transcriptional promoter which may respond to temperature or nutrient requirements. (See especially column 6) In addition, the reference discloses the system can contain one or more suicide genes such as hok, gef, relF, streptavidin genes or avidin genes. (See especially column 5, lines 27-43)

It is noted that claims 27-29 are directed to a method of making a cell strain. However, the claims contain no limitations that further distinguish the method of making the cell from the cell.

The term "vaccine" is viewed as an intended use for the cell as the claims do not contain any further limitations that distinguish the composition from the prior art.

Therefore, for the reasons recited above, the prior art disclosure is viewed as anticipating the claimed invention.

Claims 1-5, 8-14, 20, 23, 24, 27-29, and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Molin et al.

Molin et al (US Patent #5,702,916) disclose a biological containment system in which a cell containing a recombinant DNA molecule expresses a cell-killing function in certain environmental conditions. The cell killing function can be regulated by means of a promoter. (See especially Abstract; column 2, lines 30-51; column 3; column 6, lines 59-67; column 7, lines 1-22)

In addition, Molin et al disclose that the DNA can be a bacterial plasmid, or a bacterial chromosome. (See especially column 5, first paragraph)

Molin et al also disclose promoters such as λPR and PL controlled by temperature-sensitive regulating factors or lac, ara or deo promoters which are activated by the presence of lactose, arabinose and pyrimidine nucleosides, respectively. (See especially column 8)

Moreover, Molin et al disclose that the hok gene can be used since it expresses a cell-killing function when insufficient concentrations of the inhibitory sok RNA are present. (See especially column 10, lines 24-49; column 41, lines 40-64)

It is noted that claims 27-29 are directed to a method of making a cell strain. However, the claims contain no limitations that further distinguish the method of making the cell from the cell.

The term "vaccine" is viewed as an intended use for the cell as the claims do not contain any further limitations that distinguish the composition from the prior art.

Therefore, the prior art disclosure is viewed as anticipating the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to V. Ryan whose telephone number is (703)305-6558.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Papers related to this application may be submitted to the Group 1600 by facsimile transmission. The faxing of such papers

must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax number for Art Unit 1641 is (703)308-4242.

V. Ryan
Patent Examiner/Art Unit 1641
November 1998
Ryan/vr

James C. Housel
JAMES C. HOUSEL 11/9/98
SUPERVISORY PATENT EXAMINER